

REMARKS

I. INTRODUCTORY REMARKS

The Applicant greatly appreciates the time taken by the Examiner to conduct the interview on January 4, 2008. Claims 23-67 and 69-83 are pending in the application. By this Amendment, claims 43 and 44 are amended to correct minor informalities and to more particularly recite the features of the method for making a medicated device. No new matter is added and the claims have not been narrowed. In view of the foregoing amendments and following remarks, it is believed that the application is in condition for allowance. Reconsideration and withdrawal of the outstanding rejections are respectfully requested.

II. INFORMATION DISCLOSURE STATEMENT

On April 18, 2007, the Applicant filed a Request for Continued Examination (RCE) including a Fifth Information Disclosure Statement (IDS). It is respectfully requested that the information included therein be expressly considered by the Examiner, and that the listed documents be made of record such that they will appear among the "References Cited" on any patent to issue from the subject application.

Furthermore, submitted herewith is a Sixth IDS. The Applicant respectfully requests consideration of the listed document.

III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Claims 23-52, 56-59, 61-65, 67, 69-71, 74- 76-78 and 80-83 (Eder in view of Whitbourne)

In numbered paragraphs 4-9 on pages 2-5 of the Office Action dated August 23, 2007, claims 23-52, 56-59, 61-65, 67, 69-71, 74- 76-78, and 80-83 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,980,550 to Eder *et al.* ("Eder") in view of U.S. Patent No. 6,110,483 to Whitbourne *et al.* ("Whitbourne"). The rejection is respectfully traversed. Reconsideration and withdrawal of the rejections of these claims are respectfully requested.

Claim 61, for example, recites:

A medicated device comprising:
*a substrate comprising adjacent edges or surfaces
in close proximity to each other defining an opening; and*

a coating bridging from one edge or surface of the substrate to another across the opening, and said coating comprising at least one polymer and at least one therapeutic agent at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent when implanted in a patient's body. (emphasis added).

Thus, claim 61 requires "a coating bridging from one edge or surface of the substrate to another across the opening." Claims 23, 43, 45, 50, and 77 each recite similar features.

The Office Action cites the schematic cartoon depicted in FIG. 2 of Eder as ostensibly teaching or suggesting the recited "bridging." Specifically, in numbered paragraph 5 on page 3, the Office Action states:

The implant has a coil shape where the edges of the coils form opening [*sic*] between them. The edges are bridges [*sic*] by the coating material (Figure 2 204). The coating connects the edges of the coils (Figure 2).

The Applicant, however, respectfully disagrees and submits that Eder does not teach or suggest such bridging. Although drawings and pictures can be used as prior art where they clearly show the claimed structure, it is also well established that the teachings of all relevant references must be evaluated and applied "on the basis of what they *reasonably* disclose and suggest to one skilled in the art." *In re Aslanian*, 590 F.2d 911, 914, 200 USPQ (BNA) 500 (CCPA 1979) (quoting *In re Baum*, 374 F.2d 1004, 1009, 153 USPQ 190, 195 (CCPA 1967)). Thus, notwithstanding that which the schematic cartoon of FIG. 2 may appear to depict, the Applicant respectfully submits that Eder, when taken *as a whole* (i.e., including both the written disclosure and the drawings), cannot be reasonably read to teach or suggest a coating bridging from one edge or surface of the substrate to another across the opening for at least the following two reasons.

First, it is respectfully submitted that FIG. 2 of Eder is a flawed schematic illustration or cartoon of the helically wound coil 202 having an inner coating 204 and an outer coating 206 described, for example, in column 4, lines 12-14 and 58-62. FIG. 2 ostensibly attempts to show a side perspective view of the coil 202 with a cross-section of the coating thereon to illustrate the first and second layers 204, 206. The three-dimensional nature of the coil, however, does not appear to have been taken into account when the cross-section of the dual-layer coating was added by the

draftsperson. A declaration under 35 C.F.R. § 1.132 of Ms. Alexandra M. Chamberlain is submitted herewith traversing the rejection as well as the Office's interpretation of the purported teachings of Eder. Based on a fair and reasonable reading of Eder, it is Ms. Chamberlain's opinion that FIG. 2 does not teach or suggest "bridging." It is also Ms. Chamberlain's opinion, based on a reasonable understanding of that which is described and depicted in Eder, that a proper side perspective view of the coil showing the two-layer coating in cross-section would actually look something like that shown in the drawing attached to her declaration as **Appendix B**. The drawing in **Appendix B** was generated by the Applicant based on a reasonable reading of the disclosure of Eder.

Second, the written disclosure of Eder appears to teach away from the interpretation of FIG. 2 espoused in the Office Action, i.e., that the coating 204, 206 "bridges" the openings created between the individual windings of the coil 202. In column 3, lines 44-46, Eder states that "[p]referably, the inner and outer coatings do not affect the shape of said vaso-occlusive member after deployment." *See also* column 5, lines 61-63 and claim 14. This statement demonstrates that the Office's proposed interpretation of FIG. 2 is incorrect. The clear textual statement should be weighted more heavily than an incorrect, or at best ambiguous schematic cartoon that was not intended to depict the feature at issue here. Clearly, any "bridging" between individual windings of the coil 202 would affect the shape of the coil by, for example, creating a cylindrically shaped device. Accordingly, a fair and reasonable reading of Eder does not permit FIG. 2 to be interpreted as teaching or suggesting any "bridging" of the coating.

In addition to the foregoing deficiencies in Eder, the Office Action also acknowledges that Eder is "silent to the active agent loading of the implant." Page 3, numbered paragraph 5. This is apparently in reference to the recitations in various claims of a particular loading amount of the therapeutic agent in the coating. The Office Action states, however, that "[t]his loading is well known in the art" and cites Whitbourne as purportedly supporting this assertion. *Id.* More specifically, the Office Action states that "[t]he coating composition has a thickness of about less than 50 microns" (citing column 7, lines 15-20 of Whitbourne) and argues that "[a]ccording to applicant's specification a 10-micron thick coating would correspond to a 1000 microgram/cm³ [*sic*]" such that "[t]he thickness of this coating would possess a loading amount well within the limits of the claimed invention." Pages 3-4, numbered paragraph 6.

In response, the Applicant respectfully submits that neither Eder nor Whitbourne, alone or in combination, teaches or suggests the recited loading amounts and further submits that the proposed deductive reasoning is both unclear and unsupported. Notwithstanding the fact that Whitbourne purportedly discloses that the "coatings of the invention may be thin, on the order of 2 to 100 microns, preferably less than about 50 microns" (column 7, lines 15-16), there is nothing in Whitbourne or Eder that supports the assertion in the Office Action that such a coating would possess a loading amount "well within the limits of the claimed invention." Additionally, the Applicant is unclear where the Office Action finds support in the cited references for the statement that "a 10-micron thick coating would correspond to a 1000 microgram/cm³" loading or the statement that "the Whitbourne reference provides a coated stent comprising at least 1000mg per square inch of the coated surface" (Office Action, page 7, numbered paragraph 15). Interestingly, the former statement follows a citation to "applicant's specification" and, in this regard, the Office Action appears to be improperly attempting to use the instant disclosure to reach a hindsight conclusion which is entirely unsupported by the applied references, Eder and Whitbourne. Accordingly, the Applicant respectfully submits that neither Eder nor Whitbourne, alone or in combination, teaches or suggests the loading amounts recited in the various claims. The Examiner is asked to clarify the foregoing arguments in the event the rejection is maintained.

In numbered paragraph 6 on page 4, the Office Action also states, citing column 4, lines 18-30 of Whitbourne, that "[t]hough silent to the specific design of the substrates regarding their edges and surfaces, the coating is a continuous coating over each surface." The Office Action then states that "Applicant is invited to provide evidence that the continuous coating of the invention [doesn't] cover the edges and bridge the surfaces." It is respectfully submitted, however, that it is the Examiner that bears the initial burden of factually supporting any *prima facie* conclusion of obviousness and, for this reason as well, the Applicant traverses the Office Action. The Applicant is under no obligation to submit evidence that the coating disclosed in Whitbourne does not "cover the edges and bridge surfaces." Nevertheless, the cited portion of Whitbourne only states, in relevant part, "a thin continuous layer over the substrate," and the coating is later described at column 7, lines 15-17 as "a continuous *surface* layer." The Applicant submits that the conventional meaning of "continuous" does not, by itself, teach or suggest "bridging." Thus, contrary to the Examiner's

position, because Whitbourne does not describe coatings on substrates with edges in close proximity to each other, it cannot teach or suggest a coating that bridges openings.

Claims 50, 53-55, 60, 61, 66, 72-75, 77, and 79 (Eder and Whitbourne, further in view of Kamath and Khan)

In numbered paragraphs 10-14 on pages 5-6 of the Office Action, claims 50, 53-55, 60, 61, 66, 72-75, 77, and 79 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the proposed combination of Eder and Whitbourne, further in view of U.S. Patent No. 6,335,029 to Kamath *et al.* ("Kamath") and U.S. Patent No. 5,589,120 to Khan *et al.* ("Khan"). The rejection is respectfully traversed. Neither one of Kamath nor Khan is believed to remedy the above-noted deficiencies of Eder and/or Whitbourne, particularly with regard to the feature of a coating, formulation, or containing means "bridging from one edge or surface to another across an opening" as substantially recited in at least claims 23, 43, 45, 50, 61, and 77. With regard to Kamath, the Office Action cites a portion which purportedly describes an "implantable medical device having a structure adapted for introduction into a patient, e.g., a stent, coil, catheter, etc.," and which may have "at least one composite layer of a bioactive agent and a polymer material and at least one barrier layer positioned over the composite layer or layers." Kamath, column 2, lines 45-52. Like Whitbourne, this recitation does not teach or suggest a coating bridging from an edge or surface to another across an opening. Similarly, Khan is purportedly directed to a process of making a shaped tip on a catheter (*see* Title) and does not teach or suggest a coating bridging from an edge or surface to another across an opening. Claims 53-55, 60, 66, 72-75, and 79 depend variously from at least one of claims 23, 43, 45, 50, 61, and 77 and are, therefore, believed to be allowable for at least the same reasons. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. CONCLUSION

Claims 23-67 and 69-83 are pending in the application. In view of the foregoing amendments and remarks Applicant believes that a full and complete reply has been made to the Office Action dated August 23, 2007. Accordingly, the present application is believed to be in condition for allowance.

If the Examiner believes, for any reason, that a personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Prompt and favorable consideration on the merits is respectfully requested.

Respectfully submitted,



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Michael A. Gollin
Registration No. 31,957
Ryan M. Flandro
Registration No. 58,094
VENABLE LLP
P.O. Box 34385
Washington, D.C. 20043-9998
Telephone: (202) 344-4000
Telefax: (202) 344-8300

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